DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 1, 2015

Motion Composites
c/o Edward A. Kroll
Spectre Solutions, Inc.
5905 Fawn Lane
Cleveland, OH 44141

Re: K143101
Trade/Device Name: Helio A7 Manual Wheelchair and Move Manual Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical Wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: March 23, 2015
Received: March 24, 2015

Dear Mr. Kroll,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143101

Device Name
Helio A7 and Move Manual Wheelchairs

Indications for Use *(Describe)*
The indications for use of the Helio A7 and Move Manual Wheelchairs is to provide mobility to persons limited to a sitting position.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Motion Composites
Helio A7 and Move Manual Wheelchairs
510(k) Summary
(Modified 5/1/2015)

I. SUBMITTER

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II. DEVICE

Name of Device: Helio A7 and Move Manual Wheelchair
Common or Usual Name: Manual Wheelchair
Classification Name: Wheelchair, Mechanical (21 CFR 890.3850)
Regulatory Class: I
Product Code: IOR

III. PREDICATE DEVICE

Sunrise Medical Quickie 2 Manual Wheelchair K123975

IV. DEVICE DESCRIPTION

The Motion Composites Helio A7 and Move Manual Wheelchairs are manually operated, user propelled, manual, mechanical wheelchairs. Their intended function and use is to provide mobility to persons limited to a sitting position.

Both are traditional folding cross-brace wheelchairs. They are made of an aluminum frame which utilizes one cross brace system that, when opened, nestles inside of the frame onto 4 hooks to create a box like rigid assembly. Upon the outside of this framework, and to the rear, are assembled two aluminum axle plates. Wheels of varying size and type are connected to the stainless steel axle receivers via stainless steel axles.

On the front end of the frame are assembled two aluminum caster housings. Caster forks are mounted to these housings via steel axles. A variety of caster wheels and tires are then connected to the fork based on user preference.

Device Function

Device function is dependent solely upon the wheelchair user. It does not function on its' own in any manner. The wheelchair user controls motion, speed and direction by propelling themselves using the hand rims located on the rear wheels.

Scientific Concepts

There are no complex scientific concepts related to the Helio A7 and Move manual wheelchair. They are simple, basic, manually operated mobility devices.

Significant Physical and Performance Characteristics:

Design:

- The Helio A7 and Move utilize a monocoque aluminum frame that is entirely welded and heat threated for greatly improved rigidity over regular interconnected side frames.

- A completely symmetrical aluminum cross-brace connects the left and right mono side frames of the wheelchair together and serves as the mechanism that allows the frame to fold.

- A set of adjustable axle plates are attached vertically to each side frame and provide the wheelchair with ability to move the rear wheel position forward and backward in order to give the user an adjustment as to the center of gravity of the wheelchair. This rear axle vertical position limits torsion and flexion for improved propulsion.

Materials:

Materials used are:

- Aluminum frame, support members, wheels and components
- Steel fasteners and components
- Polyurethane tires
- Fabric covered foam upholstery

Physical Properties:

The Helio A7 and Move consist primarily of an aluminum frame assembly, a back rest frame, seat and back rest upholstery, large rear wheels with hand rims for self-propelling the chairs and front swivel pivoting casters for turning.

V. INDICATIONS FOR USE

The indications for use of the A7 and Move Manual Wheelchairs are to provide mobility to persons limited to a sitting position. This identical to the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technology and principle of operation for the Helio A7 and Move and the Quickie 2 are identical. They all consist of an aluminum frame with a seat and large rear wheels with hand rims for propelling the device. Smaller, pivoting type casters are mounted on the front of the chairs for steering and turning.

Device function is dependent solely upon the wheelchair user. They do not function on their own in any manner. The wheelchair user controls motion, speed and direction by propelling themselves using the hand rims located on the rear wheels.

If both rear wheels are propelled at the same time, the chair will move forward in a straight direction. If only the left rear wheel is propelled the chair will turn to the right. If only the right rear wheel is propelled the chair will turn to the left.

Discussion of Similarities and Differences:

The Helio A7 and Move are substantially equivalent to the predicate Quickie 2 wheelchair (K123975) in technology, function, performance and materials. They have the same indications for use which is to provide mobility for persons restricted in a sitting position.

The frame width, depth and the back cane heights vary slightly between the devices, but since these are only used to better fit the device to the user's needs, these slight differences do not cause any concerns for the safety and effectiveness of the device. The weight limit is the same for all devices and is clearly stated in the proposed device labeling.

With regard to accessories and add-ons, all devices offer the same types of armrests, backrests, hangers and footplates. These accessories are made of the exact same materials for all devices and thus do not raise any questions for the safety and effectiveness of the Helio A7 and Move wheelchairs. The same can be said of back types and extension tubes.

Axle plates for all devices are made out of the same material, however, the actual mounting systems differ slightly. Where the Quickie 2 axle plate is mounted horizontally on the frame, the Helio A7 and Move are mounted vertically.

This mechanical change permits better handling and propulsion by reducing the inwards flexion of the wheel during wheel pushes. It does not raise any concerns for the safety and effectiveness of the device and actually augments the effectiveness of the Helio A7 and Move when compared to

the predicate device. This mounting system is a patented technology exclusive to Motion Composites.

The same can be said for the caster housing that holds the front wheel into place. While the caster housing of the predicate device and those of the Helio A7 and Move are made all made of aluminum, the mounting system of the Helio A7 casters housing is patented and thus slightly different from the one found on the Quickie 2 wheelchair.

This mounting system embeds the caster housing directly into the frame, reducing the effects of wear and tear by minimizing the amount of parts used to fasten the caster to the frame, thus providing a better overall experience to the wheelchair user.

This change as well does not raise any concerns as far as the safety of the overall product against the predicate device, since all casters offer the same effectiveness as per the Helio A7 successfully obtaining its ISO certification. As for the Move caster housing, it uses the same exact design and function as the predicate device.

The seat and back upholstery offering of the Helio is equivalent to the one found on the predicate device. It is made of high-quality durable sailcloth, which consists of 1000 denier fill and 250 denier wrap.

The rear wheels and hand rims of the predicate device and the Helio A7 Move wheelchair are offered in a wide range of different options. They are made of the same materials and are widely used in the wheelchair industry. The specific type, material and size of the wheels are chosen depending on the user's needs. These differences do not raise any concerns for the safety and effectiveness of the Helio A7 and Move wheelchairs. We also note the wheel locks are the same on all devices.

Based on the above discussion, Motion Composites believes that the Helio A7 and Move wheelchairs are substantially equivalent to the Quickie 2 wheelchair (K123975). While there are some differences between the Helio A7 and Move and its predicate, these differences are minor and do not alter the intended function and use of the device, nor do they raise any new questions pertaining to safety or effectiveness.

VII. PERFORMANCE DATA

The Helio A7 and Move Manual Wheelchairs have been tested to the following standards;

- ISO 7176-1:1999 Determination of Static Stability
- ISO 7176-3:2012 Determination of Effectiveness of Brakes
- ISO 7176-5:2008 Determination of Overall Dimensions, Mass and Maneuvering
- Space
- ISO 7176-7:1998 Determination of Seating and Wheel Dimensions
- ISO-7176-8:1998 Requirements and Test Method for Static Impact and Fatigue Strength

- ISO 7176-15 Requirements for Information Disclosure, Documentation and Labeling

The upholstery used meets the requirements of Cal 117 for flammability. These are identical to the materials used in the Motion Composites Helio manual wheelchair. The Helio manual wheelchair was cleared by FDA December 19, 2012 under 510(k) Accession Number K120628.

The performance data for the Quickie 2 is not published. However, on page 6 of the Quickie 2 Owner's Manual, the following statement is made;

> "Based on ANSI/RESNA testing, Sunrise Medical recommends the use of a caster wheel with a minimum diameter of 5" if the wheelchair will be overcoming obstacles of up to ½" on a regular basis.

This statement indicates that the Sunrise Quickie 2 has been tested to at least some of the ANSI/RESNA standards. These standards are comparable to the ISO 7176 standards which were used to test the Motion Composites A7 and Move wheelchairs. (Note that a copy of the Quickie 2 Owner's Manual is provided in Volume 10 of this submission).

Further, manual wheelchairs are subject to the 1995 FDA guidance document entitled: "Guidance Document for the Preparation of Premarket Notification [(510(k)] Applications Mechanical and Powered Wheelchairs, and Motorized Three-Wheeled Vehicles." This guidance includes various safety and performance requirements that the Quickie 2 would have to have met or addressed prior to being cleared by FDA. Meeting these requirements also serves as a basis for substantial equivalence of the A7 and Move to its' predicate.

VIII. CONCLUSIONS:

Performance testing and compliance with FDA guidance for manual wheelchairs supports the safety of the Helio A7 and Move manual wheelchairs. Since the predicate device was cleared based in part on these data, conformance with the same requirements demonstrate that the Helio A7 and Move will perform as intended in the specified use conditions.

Further, technology, principle of operation and indications for use between Helio A7 and Move and the Quickie 2, are identical. This demonstrates that they perform comparably to the predicate device that is currently marketed for the same intended use. Therefore, the Helio A7 and Move manual wheelchairs are substantially equivalent to the Quickie 2 device.

Helio A7 and Move
Predicate Device Comparison

Feature/Specification	Quickie Wheelchair (K123975)	Helio A7 Wheelchair	Move Wheelchair
Intended Use	The Quickie 2 Wheelchair is a manually operated device intended to be used as a means of mobility for persons restrict to a sitting position.	The Helio A7 wheelchair is a manually operated device intended to be used as a means of mobility for persons restrict to a sitting position.	The Move wheelchair is a manually operated device intended to be used as a means of mobility for persons restrict to a sitting position.
Primary Materials	Aluminum 6000 series	Aluminum 7000 series	Aluminum 6000 series
Folding Method	Collapsible Cross-Brace	Collapsible Cross-brace	Collapsible Cross-brace
Frame Width	11” to 22”	14” to 22”	14, 16, 18, 20, 22”
Overall width	20,5” to 28,5”	21 1/2" to 29 ½”	21 1/2" to 29 ½”
Seat Depth	10” to 20”	15" to 21"	16",18",20
Back Heights	8,5” to 19”	8,5” to 19”	16", 20"
Weight Limit :	250lbs	250 lbs.	250 lbs.
Seat height :	16.75” to 22.75”.	13" to 21 1/4"	13" to 20 3/4"
Chair Weight (without footrests)	27 lbs.	16.5 lbs. (without footrests)	19 lbs. (without footrests)
Warranty	Lifetime on frame	Frame 5 years, Components 1 year	Frame 5 years, Components 1 year
Armrests	Flip back Height adjustable T-Shaped Armrests - Height adjustable Tubular Swing-away	-Flip back armrest, removable, height adjustable (by user, ne tool required) -T-Shaped armrest, removable, height adjustable (by user, no tool required) -Tubular Swing-away	-Flip back armrest, removable, height adjustable (by user, ne tool required) -T-Shaped armrest, removable, height adjustable (by user, no tool required) -Tubular Swing-away
Front end types	Swing-Away Non swing-away	Swing-Away	Swing-Away
Back Type	Standard Angle Adjustable Depth Adjustable Standard	-Straight -8 degree bend back -Adjustable angle- straight or 8 degree bend	-8 degree bend back with integrated push handle -Adjustable angle 8 degree bend with integrated push handle
Footrest Hangers	60,70,90 degrees, elevating legrests	Flip in, flip out; 60°, 70° , 90°, elevating legrest	Flip out; 60°, 70° , elevating legrest
Footplates	Composites, Foam, Aluminum angle adjustable	-Standard non adjustable -Angle Adjustable Oversized	-Standard non adjustable -Angle Adjustable Oversized
Back Upholstery	Low, Medium, Tall, Adjustable,	Standard, Adjustable	Standard, Adjustable
Axle Plates	Standard, Curved, Amputee, Offset Standard	Standard, Amputee	Standard, Amputee
Wheel sizes	20,22,25,26 “	20 ,22,24, 25, 26 "	20 ,22,24, 25, 26 "
Wheel types	Spoke, Composite Mag, Spinergy, One arm drive	-Plastic Mags -Spoke, Newton One -Spoke, Newton Gravity -Spinergy LX -Spinergy Spox	-Plastic Mags -Spoke, Newton One -Spoke, Newton Gravity -Spinergy LX -Spinergy Spox
Tire types	Pneumatic, Pneumatic w/ airless insert Polyurethane, Low Profile Full profile Iron Cap	-Pneumatic regular and high pressure -Full and low profile polyurethane -Hard Urethane	-Pneumatic regular and high pressure -Full and low profile polyurethane -Hard Urethane
Handrims	Aluminum, Plastic Coated, Projections	-Aluminum Anodized -Plastic Coated (regular or high friction) -Spinergy Flexrim -Natural Fit handrim -Surge Handrim	-Aluminum Anodized -Plastic Coated (regular or high friction) -Spinergy Flexrim -Natural Fit handrim -Surge Handrim
Caster Sizes	4”,5”,6”,8”	3" to 8"	3” to 8”

Helio A7 and Move
Predicate Device Comparison

Feature/Specification	Quickie Wheelchair (K123975)	Helio A7 Wheelchair	Move Wheelchair
Caster types	Polyurethane, semi-pneumatic, Soft Roll, Pneumatic	Composites wheels, Pneumatic, Soft Roll	Composites wheels, Pneumatic, Soft Roll
Fork Sizes	3”,4”,5”,6”,7”	3”,4”,5”,7”	3”,4”,5”,7”
Fork Stem Sizes	Std,+3/4”,+1 ½”	std, +1 , +2	std, +1 , +2
Caster Options	Multi-position fork caster, pin locks	Multi-position fork caster, pin locks	Multi-position fork caster, pin locks
Wheel Locks	Push to lock, pull to lock, scissor lock	Push to lock, pull to lock, scissor lock	Push to lock, pull to lock, scissor lock
Anti-tip tubes	Yes	Yes	Yes
Target population	Restricted to a sitting position	Restricted to a sitting position	Restricted to a sitting position
Standards	Unknown	ISO 7176 – (1, 3, 5, 7, 8 & 15)	ISO 7176 – (1, 3, 5, 7, 8 & 15)